NOV 18 2011

SYNTHES
Spine

510(k) Summary

510(k) Summary	
Name of Firm:	Synthes Spine 1302 Wrights Lane East West Chester, PA 19380
510(k) Contact:	Heather Guerin Spine Senior Regulatory Affairs Specialist Telephone: 610-719-5432 Facsimile: 610-719-5102 Email: guerin.heather@synthes.com
Date Prepared:	November 17, 2011
Trade Name:	Synthes Universal Spine System (USS)
Classification:	21 CFR 888.3050–Spinal interlaminar fixation orthosis 21 CFR 888.3060–Spinal intervertebral body fixation orthosis 21 CFR 888.3070–Pedicle screw spinal system, Class III Orthopaedic and Rehabilitation Devices Panel Product Code: NKB, MNH, MNI, KWQ, KWP
Predicates:	Synthes USS, K963045 Synthes Click'X, K992739 Synthes Click'X, K031175 Synthes USS Illiosacral and Polyaxial, K082572 Synthes Matrix System, K092929 Synthes Matrix System, K100634 Synthes Matrix System, K100952 Synthes 6.0 CoCr and CP Ti-3 Rods, K103287
Device Description:	The Synthes USS is an addition to Synthes' existing non-cervical spinal fixation devices intended for posterior pedicle screw fixation (T1-S2/ilium), posterior hook fixation (T1-L5), or anterolateral fixation (T8-L5). These components are snap-on parallel connectors which can connect spinal rods of the same or different diameters. The snap-on parallel connectors are comprised of TAN (Titanium-6 Aluminum-7 Niobium, per ASTM F1295-05) and Nitinol (per ASTM F2063-05).
Intended Use/ Indications for Use:	The Synthes USS are non-cervical spinal fixation devices intended for posterior pedicle screw fixation (T1-S2/ilium), posterior hook fixation (T1-L5), or anterolateral fixation (T8-L5). Pedicle screw fixation is limited to skeletally mature patients with the exception of the Small Stature USS, which includes small stature and pediatric patients. These devices are indicated as an adjunct to fusion for all of the following indications: degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (*i.e.*, fracture or dislocation), deformities or curvatures (*i.e.*, scoliosis, kyphosis, and/or lordosis, Scheuerrnann's

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JAN 12 2012

Synthes Spine
% Ms. Heather Guerin
1302 Wrights Lane East
West Chester, Pennsylvania 19380

Re: K111358
Trade/Device Name: Synthes USS
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Code: NKB, MNI, MNH, KWP, KWQ
Dated: September 20, 2011
Received: September 21, 2011

Dear Ms. Guerin:

This letter corrects our previous letter dated November 18, 2011, which cited incorrectly the Trade/Device Name for the subject device.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SYNTHES®
Spine

Indications for Use Statement

510(k) Number: K111358
Device Name: Synthes Universal Spine System (USS)

The Synthes USS are non-cervical spinal fixation devices intended for posterior pedicle screw fixation (T1 -S2/ilium), posterior hook fixation (T1-L5), or anterolateral fixation (T8-L5). Pedicle screw fixation is limited to skeletally mature patients with the exception of the Small Stature USS, which includes small stature and pediatric patients. These devices are indicated as an adjunct to fusion for all of the following indications: degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (*i.e.*, fracture or dislocation), deformities or curvatures (*i.e.*, scoliosis, kyphosis, and/or lordosis, Scheuermann's Disease), tumor, stenosis, and failed previous fusion (pseudoarthrosis).

When treating patients with Degenerative Disc Disease (DDD), transverse bars are not cleared for use as part of the posterior pedicle screw construct.

When used with the 3.5/6.0mm parallel connectors, the Synthes USS 6.0mm rod systems can be linked to the CerviFix 3.5mm Systems. In addition, when used with 3.5/5.0mm parallel connectors, the Synthes Small Stature USS can be linked to the CerviFix 3.5mm Systems. When used with the 5.0/6.0mm parallel connectors, the Synthes Small Stature USS can be linked to the Synthes USS 6.0mm rod systems. When used with the 5.5/6.0mm parallel connectors, Matrix can be linked to the Synthes USS 6.0mm rod systems. 6.0/6.0mm parallel connectors can be used to link all Synthes USS 6.0mm rod systems to one another.

When used with the 3.5/6.0mm and 4.0/6.0mm tapered rods, the Synthes USS 6.0mm rod systems can be linked to the CerviFix 3.5mm and 4.0mm Systems, respectively. When used with the 3.5/5.5mm and 4.0/5.5 mm tapered rods, Matrix can be linked to the CerviFix 3.5mm and 4.0mm Systems, respectively. When used with the 5.5/6.0mm tapered rods, the Synthes USS 6.0mm rod systems can be linked to the Matrix System.

In addition, Synthes USS 6.0mm rod systems can be interchanged with all USS 6.0 mm rods and transconnectors except Synthes 6.0mm cobalt-chromium-molybdenum alloy and titanium grade 3 rods, which can only be used with Pangea.

Synthes USS

- 6.0mm Rod Systems: USS Side-Opening, USS Dual-Opening, USS VAS variable axis components, USS Fracture, Click'X, Click'X Monoaxial, Pangea, Pangea Monoaxial, USS Polyaxial, USS Iliosacral, ClampFix
- 5.5mm Rod System: Matrix
- 5.0mm Rod System: USS Small Stature

CerviFix

- 3.5mm Rod Systems: CerviFix, Axon, Synapse
- 4.0mm Rod System: Synapse

Prescription Use X (21 CFR 801 Subpart D)	AND / OR	Over-the-Counter Use (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K111358